

## Overview

Mental illness is a leading cause of disability in our country, costing the U.S. an estimated \$300 billion a year.<sup>i</sup> Many of the one in five<sup>ii</sup> Americans living with a mental health condition recover, work, have families and lead full lives. But many others have complex or treatment-resistant conditions that do not respond to available treatments.

There is an urgent need for new medications to treat the wide array of mental health conditions. Existing medications can be helpful, but they often have significant limitations; in some cases requiring weeks to take effect, failing to relieve symptoms in a significant proportion of people or resulting in debilitating side effects. However, developing new medications is a lengthy and expensive process. Many promising compounds fail to prove effective in clinical testing after years of preliminary research.

We need to rapidly accelerate the pace of drug discovery through an ‘experimental medicine’ approach to evaluate novel interventions for mental illnesses. Collaboration between government-funded research and the private sector is needed to move forward on a “fast-fail” strategy that is designed to quickly identify targets that merit more extensive testing. In addition, engagement with the FDA is needed to identify and validate biomarkers for disorders such as schizophrenia.

Finally, Congress must build on the success of the *21<sup>st</sup> Century Cures Act* that was passed in 2016 to advance medical discoveries and create a regulatory framework that ensures that patients can get access to innovative therapies. The important investments in research in the *Cures* law – in particular, funding for the BRAIN Initiative (Brain Research through Advancing Innovative Neurotechnologies) – offer enormous promise. These efforts will be severely undermined if Congress fails to sustain funding at the NIH or pass the FDA user fee agreements before they expire.

## NAMI’s asks

- **Support increased investment in the National Institutes of Health (NIH)**  
NAMI supports \$36.2 billion for NIH in FY 2018. This \$2 billion increase to the NIH base would enable real growth over biomedical inflation as an important step to stabilizing the nation’s research capacity over the long term.
  - For the National Institute of Mental Health (NIMH), NAMI supports an increase above the FY 2017 funding level of \$1.602 billion with continuation of the \$6 million Early Psychosis Intervention Network (EPINET) program.
  - NAMI also supports continued funding for the BRAIN Initiative above the current funding level of \$260 million.
- **Support timely passage of S. 934 / H.R. 2430, the FDA Reauthorization Act, before the current user fee agreements for prescription drugs and medical devices expire on September 30, 2017.** Failure to pass this legislation will result in as many as one-third of the clinical review staff at the FDA to be laid off. This would abruptly impact approval of new medications and surveillance of ongoing safety reviews, compromising the agency’s role as the world’s leading public health agency.

## Facts about mental illness

- Over 40,000 American lives are lost each year to suicide,<sup>iii</sup> making it the 2<sup>nd</sup> leading cause of death for Americans age 15-24 and the 10<sup>th</sup> leading cause of death for adults.<sup>iv</sup>
- Between 10%-30% of people with major depression do not respond to typical antidepressant medications.
- Mental illness is the third most costly medical condition in terms of overall health expenditures, behind only cancer and traumatic injury.<sup>v</sup>
- The cost of mental illness is only expected to sharply increase, not decrease over the coming decades.<sup>vi</sup>
- Without investment in research and appropriate services and supports, the social and economic costs associated with mental health conditions are enormous. Communities devote enormous resources to addressing the human and financial cost of untreated illness through law enforcement, homeless shelters and emergency medical services.

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<sup>i</sup> National Institute of Mental Health (2017). *Annual Total Direct and Indirect Costs of Serious Mental Illness (2002)*. Retrieved from: <https://www.nimh.nih.gov/health/statistics/cost/index.shtml>.

<sup>ii</sup> National Institute of Mental Health. (2017) *Any Mental Illness (AMI) Among U.S. Adults*. Retrieved from: <http://www.nimh.nih.gov/health/statistics/prevalence/any-mental-illness-ami-among-adults.shtml>.

<sup>iii</sup> Center for Disease Control and Prevention (2015). *Suicide Facts at a Glance 2015*. Retrieved from: <http://www.cdc.gov/violenceprevention/pdf/suicide-datasheet-a.pdf>.

<sup>iv</sup> Center for Disease Control and Prevention (2015). *10 Leading Causes of Death By Age Group, United States, 2015*. Retrieved from: [https://www.cdc.gov/injury/images/lc-charts/leading\\_causes\\_of\\_death\\_age\\_group\\_2015\\_1050w740h.gif](https://www.cdc.gov/injury/images/lc-charts/leading_causes_of_death_age_group_2015_1050w740h.gif).

<sup>v</sup> Soni, A. (2015). *Top Five Most Costly Conditions among Adults Age 18 and Older, 2012: Estimates for the U.S. Civilian Noninstitutionalized Population*. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. Retrieved from: [https://meps.ahrq.gov/data\\_files/publications/st471/stat471.shtml](https://meps.ahrq.gov/data_files/publications/st471/stat471.shtml).

<sup>vi</sup> Bloom, D.E., Cafiero, E.T., Jané-Llopis, E., Abrahams-Gessel, S., Bloom, L.R., Fathima, S., Feigl, A.B., Gaziano, T., Mowafi, M., Pandya, A., Prettnner, K., Rosenberg, L., Seligman, B., Stein, A.Z., & Weinstein, C. (2011). *The Global Economic Burden of Noncommunicable Diseases*. Geneva: World Economic Forum. Retrieved from: [http://www3.weforum.org/docs/WEF\\_Harvard\\_HE\\_GlobalEconomicBurdenNonCommunicableDiseases\\_2011.pdf](http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf).